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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/334,325	06/16/1999	STEWART A. CEDERHOLM-WILLIAMS	CV0276A	5209

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/334,325	CEDERHOLM-WILLIAMS, STEWART A.	
	Examiner	**Art Unit**	
	Shin-Lin Chen	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): 102/103 rejection of claim 17.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: *None*.

Claim(s) rejected: *1 and 13-16*.

Claim(s) withdrawn from consideration: *None*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the claims are not directed to gene therapy in vivo and the rejection does not say that transforming a cell is unpredictable. Applicant further argues that transforming a cell in vivo is enabled and one skilled in the art would know how to measure the transformation (amendment, p. 3, 4). This is not found persuasive because of the reasons set forth in the preceding Official actions mailed 3-12-03 (Paper No. 22) and 9-8-03 (paper No. 25). As discussed before, the claims read on applying a nucleic acid to cells in vivo so as to transform cells and the transformation of cells in vivo must have a use, which is to provide therapeutic effect in vivo. The title of the present invention reads "Fibrin sealant as a transfection /transformation vehicle for gene therapy". Therefore, the claims read on gene therapy in vivo, which was unpredictable at the time of the invention. Further, the specification fails to provide adequate guidance and evidence for how to administer a nucleic acid to cells in vivo and apply a pliable, adhesive fibrin gel to said cells such that the cells are transformed and therapeutic effects are obtained i vivo via various administration routes to different target cells. The specification fails to provide adequate guidance what apparatus is used to deliver the pliable, adhesive fibrin gel to target cells in a subject for transformation of said cells. It was known in the art that the pliable, adhesive fibrin gel will polymerize quickly. The specification indicates that "Generally, the sealant mixture remains conveniently pliable fo about 30 seconds or less" (page 17, lines 16, 17). The pliable, adhesive fibrin gel could solidify before the fibrin gel reach the target cells with administered nucleic acid. There is no evidence of record that shows transformation of target cells in a subject with any nucleic acid via administering the pliable, adhesive fibrin gel to said cells so as to provide therapeutic effect in vivo. Applicant argues that the 35 U.S.C. 112 first enablement rejection in the Official action is in fact a utility rejection and the rejection does not explain a scientific basis to doubt the applicant's utility that is specific, subtantial and credible (amendment, p. 4-6). This is not found persuasive because of the reasons set forth in the preceding Official actions mailed 3-12-03 (paper No. 22) and 9-8-03 (paper No. 25). The 35 U.S.C. 112 first paragraph enablement rejection is not a 35 U.S.C. 101 rejection, gene therapy in vivo is considered the utility of the present invention. Applicant's argument regarding the 35 U.S.C. 101 rejection is irrelevant. Further, the Official actions set forth above do provide scientific explanation why administering nucleic acid to cells in vivo via the claimed method of the present invention for gene therapy would be unpredictable at the time of the invention and it would have required one skilled in the art at the time of the invention undue experimentation to practice the full scope of the invention claimed. The specification must provide sufficient enabling disclosure for the claimed invention but fails to do so. Therefore, claims 1 and 13-16 remain rejected under 35 U.S.C. 112 first paragraph .